



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/580,415

04/03/2007

Norimasa Miura

060387

6081

23850 7590 09/03/2008
KRATZ, QUINTOS & HANSON, LLP
1420 K Street, N.W.
Suite 400
WASHINGTON, DC 20005

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,415	MIURA ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' response to the office action field on May 12, 2008 has been considered and acknowledged.

Status of the Application

2. Currently claim 1 is pending. Claim 2 is cancelled. Applicants' arguments have been fully considered and deemed persuasive for the reasons that follow.

Sequence Rules and Objection to the Specification

3. The specification is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825. The instant application recites sequences that are not identified by SEQ ID No. (see at least newly amended abstract) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Examiner also notes that the application contains no sequence listing either in the form of a paper copy or in a computer readable form. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cech et al. (US 6,475,789).

Cech et al. teach a cancer diagnostic method of claim 1 comprising a process to obtain the sample containing RNA only as a cell fraction from a body fluid (see col. 4, line 6-28, col. 79, line 13-25); selectively extracting RNA from the cell fraction (see col. 80, line 22-49), and a process having a reverse transcription reaction step to generate cDNA using reverse transcriptase from the sample containing said RNA only (see col. 80, line 37-47, col. 105, line 25-38 and a PCR step utilizing fluorescent dye (SYBR green I) using the primers for hTERT (LT5), CGGAAGAGTGTCTGGAGCAA , and (LT6) GGATGAAG CGGAG TCTGGA to quantify said PCR product amplified by PCR reaction using the fluorescent dye binding to the PCR product and quantitatively measuring the fluorescence of the fluorescent dye binding to the PCR product (see col. 105, line 39-57, Table 2 for the primers LT5 and LT6). Accordingly Cech et al. anticipates the instant claim.

Response to arguments:

5. With regard to the objection to the specification, Applicants' arguments and amendment (abstract and sequence identifiers) were fully considered and found persuasive and the objection to the specification is withdrawn however the newly amended abstract recites nucleic acid sequences that are not represented by sequence identifiers and therefore the objection is rewritten as above.

6. With regard to the objection to the Oath/declaration, Applicants' arguments and the newly submitted Oath/declaration were fully considered and the objection is withdrawn herein.

7. With regard to the informalities, Applicants' arguments and the amendment were fully considered and the objection to the informalities is withdrawn herein in view of the amendment and arguments.

8. With regard to the rejection of claim 1 under 35 USC 102(b) as being anticipated by Kanaya et al., Applicants' arguments and amendment were fully considered and found persuasive in view of the arguments drawn to bodily fluids.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

Application/Control Number: 10/580,415
Art Unit: 1637

Page 5